

REMARKS

Claims 1-6, 9-14 and 17-19 were pending in the present application. Claim 1 has been amended. Support for the amendment to claim 1 can be found in the specification at least at page 32, lines 28-29. Thus, upon entry of this amendment, claims 1-6, 9-14 and 17-19 are pending in the application.

No new matter has been added. The foregoing claim amendment should in no way be construed as an acquiescence to any of the Examiner's rejections and were made solely to expedite prosecution of the present application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Double Patenting Rejection of Claims 1-6, 9-14, and 17-19

Claims 1-6, 9-14, and 17-19 are rejected under the judicially created doctrine of nonstatutory obvious-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,888,981. Applicants submit herewith a terminal disclaimer in compliance with 37 C.F.R. §1.321 (c), accompanied by the appropriate fee of \$110.00 each, as required by 37 C.F.R. § 1.20(d). Accordingly, Applicants respectfully request that the obviousness-type double patenting rejections of claims 1-6, 9-14, and 17-19 be reconsidered and withdrawn. The filing of this terminal disclaimer should in no way be construed as an acquiescence to the Examiner's obviousness-type double patenting rejections and was done solely to expedite the prosecution of the application.

Rejection of Claims 1, 6 and 9 under 35 U.S.C. § 112, First Paragraph

Claims 1, 6 and 9 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that the instant specification "does not reasonably provide enablement for the claimed wherein the cell is present in a subject *in vivo* and one or both the nucleic acids are administered to a subject and the second nucleic acid is present in a cell." The Examiner also states that the specification is enabling for, "a method of regulating

expression of a tet operator-linked gene in a cell, wherein a first nucleic acid molecule comprises the tet operator-linked gene whereas a second nucleic acid nucleic acid [sic] encodes a tetracycline-controllable transactivator tTA...wherein the method is carried out... in vivo wherein both the nucleic acids are administered directly to the cell."

Applicants respectfully traverse this rejection and maintain that in view of the specification and the general knowledge in the art, evidenced by the previous reference submissions, the specification has provided sufficient guidance to the ordinarily skilled artisan to make and use the invention. However, in the interest of expediting prosecution of the application, claim 1 has been amended to recite that the first nucleic acid molecule comprising the *tet* operator-linked gene is directly introduced into the cell and that the second nucleic encoding the tTA molecule is directly introduced into the cell. In view of the amendment to claim 1, Applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection of claims 1, 6, and 9.

SUMMARY

In view of the foregoing remarks, reconsideration of the rejections and allowance of all pending claims is respectfully requested.

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the examiner is urged to call Applicants' Attorney at (617) 227-7400.

Respectfully submitted,



DeAnn F. Smith, Esq.
Reg. No. 36,683
Attorney for Applicant

LAHIVE & COCKFIELD, LLP
28 State Street
Boston, MA 02109
Tel. (617) 227-7400
Dated: January 21, 2004